General

Guideline Title

Management of atopic eczema in primary care. A national clinical guideline.

Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of atopic eczema in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2011 Mar. 34 p. (SIGN publication; no. 125). [62 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A–D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Diagnosis, Referral and Patient Education

Referral

D - An emergency referral to a dermatologist or paediatrician should be arranged by telephone where there is clinical suspicion of eczema herpeticum (widespread herpes simplex).

D - Patients should be referred to a dermatologist where there is:

- Uncertainty concerning the diagnosis
- Poor control of the condition or failure to respond to appropriate topical treatments
- Psychological upset or sleep problems
- Recurrent secondary infection

Emollient Therapy

Effectiveness

C - Patients with atopic eczema should have ongoing treatment with emollients.

Topical Corticosteroid Therapy

Effectiveness

A - Patients should be advised to continue with emollient therapy during treatment with topical corticosteroids.

Once versus Twice Daily Application

B - Patients with atopic eczema should be advised to apply topical corticosteroids once daily.

Maintenance Therapy

A - Twice weekly maintenance therapy with a topical corticosteroid should be considered in patients with moderate to severe atopic eczema experiencing frequent relapses.

Adverse Effects

B - Topical corticosteroids should be used with caution in the periocular region.

Topical Calcineurin Inhibitors

C - Topical tacrolimus should be considered, in patients aged two years and older, for short term, intermittent treatment of moderate to severe atopic eczema that has not been controlled by topical corticosteroids or where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly skin atrophy.

Antimicrobial Measures

Effectiveness of Antimicrobial Measures

Oral Antibiotics

B - Oral antibiotics are not recommended in the routine treatment of non-infected atopic eczema.

Dietary Interventions

Food Allergy and Dietary Exclusion

C - Dietary exclusion is not recommended for management of atopic eczema in patients without confirmed food allergy.

Infant Feeding

Maternal Food Antigen Avoidance

A - The exclusion of foods during pregnancy and breast feeding to prevent the development of atopic eczema in infants is not recommended.

Breast Feeding

B - Parents should be advised that exclusive breast feeding for three months or more may help prevent the development of infant eczema where there is a family history of atopy.

Formula Feeding

B - Hydrolysed formulas should not be offered to infants in preference to breast milk for the prevention of atopic eczema.

Definitions:

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review, or randomised controlled trial (RCT) rated as 1++, and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+: Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Atopic eczema

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Allergy and Immunology

Dermatology

Family Practice

Internal Medicine

Nursing

Nutrition

Pediatrics

Intended Users

Advanced Practice Nurses

Dietitians

Nurses

Patients

Pharmacists

Physicians

Guideline Objective(s)

To provide recommendations for the management of atopic eczema in children and adults in primary care, based on current evidence for best practice

Target Population

Adults and children with atopic eczema

Interventions and Practices Considered

Diagnosis/Evaluation

1. Patient history and visual assessment
2. Assessment of severity and patient quality of life
3. Emergency referral to a dermatologist or paediatrician as appropriate

Treatment/Management

1. Emollient therapy
2. Topical corticosteroid therapy
3. Topical calcineurin inhibitors (tacrolimus)
4. Dressings and wet wrap treatment
5. Oral antibiotics (not recommended routinely)
6. Antihistamines
7. Management of environmental factors (no recommendations could be made because of insufficient evidence)
8. Dietary exclusions (not recommended in patients without confirmed food allergy)

9. Advice to breast feed infants
10. Use of hydrolysed formulas for infant feeding (considered but not recommended in preference to breast feeding)
11. Complementary and alternative therapies (considered but not recommended)

Major Outcomes Considered

- Improvement in skin condition
- Severity of eczema
- Rate of relapse
- Adverse effects of treatments

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Databases searched included Medline, Embase, Cinahl, PsychInfo and the Cochrane Library. The year range was 2004-2009. The main searches were supplemented by material identified by individual members of the development group, including key reviews from outside the search period. Each of the selected papers was evaluated by members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

Patient Issues

At the start of the guideline development process, a SIGN Information Officer conducted a standard SIGN literature search for qualitative and quantitative studies that addressed patient issues of relevance regarding atopic eczema, with a date range 2002-2008. A further search was conducted on patient and social aspects. The results of the two searches were summarised and presented to the guideline development group to inform them of key patient issues for consideration when devising the key questions. Databases searched include Medline, Embase, Cinahl and PsychInfo.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site .

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, Scottish Intercollegiate Guidelines Network (SIGN) has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of study findings
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the National Health Service (NHS) in Scotland to implement the recommendation.)

The group are finally asked to summarise its view on all of these issues, both the quality of the evidence and its potential impact, before making a graded recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site .

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review, or randomised controlled trial (RCT) rated as 1++, and directly applicable to the target population; *or*

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B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D:: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

National Open Meeting

A national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held on 1 October 2009 and was attended by 157 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

Specialist Review

This guideline was also reviewed in draft form by independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The guideline group addresses every comment made by an external reviewer, and must justify any disagreement with the reviewers' comments (see Section 16 of the original guideline document for a listing of the independent reviewers).

SIGN Editorial Group

As a final quality control check, the guideline is reviewed by an editorial group including the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of atopic eczema in primary care patients may lead to improved treatment outcomes, quality of life, and cost-effectiveness of treatment.

Potential Harms

Topical Corticosteroids

The local adverse effects of topical corticosteroid usage include skin thinning, bruising, perioral dermatitis, folliculitis, pruritus, allergic contact dermatitis and the spread of fungal infection. In a systematic review the short term use of topical corticosteroids was not associated with observable skin thinning. Topical corticosteroid usage around the eyes has been associated with glaucoma and cataracts, although the degree of risk has not been established.

Topical Calcineurin Inhibitors

- In a systematic review of randomised controlled trials, the most common adverse effects of tacrolimus and pimecrolimus were skin irritation and burning. A non-statistically significant trend towards increased incidence of infections when using topical calcineurin inhibitors (TCIs), particularly virally mediated, was noted in a systematic review of medication safety.
- There are significant concerns around increased risk of malignancy (including skin cancers and lymphomas) following TCI use, based on post-marketing surveillance reports. Since these treatments are relatively new there is insufficient evidence to make a definitive statement on whether patients with atopic eczema treated with a TCI are at an increased risk of developing malignancy. This uncertainty around long term safety profile limits the use of TCIs to moderate and severe atopic eczema and to a second line therapy.
- As a precaution against the possibility that the normal immunological response to infection may be suppressed, TCIs should not be applied to skin which appears actively infected.

Qualifying Statements

Qualifying Statements

Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions, corrections will be published in the web version of the document, which is the definitive version at all times. The version can be found on www.sign.ac.uk.

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

Prescribing of Medicines Outwith Their Marketing Authorisation

Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (product licence). This is known as 'off label' use. It is not unusual for medicines to be prescribed outwith their product licence and this can be necessary for a variety of reasons.

Generally the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines; such use should be supported by appropriate evidence and experience.

Medicines may be prescribed outwith their product licence in the following circumstances:

- For an indication not specified within the marketing authorisation
- For administration via a different route
- For administration of a different dose.

Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.*

Any practitioner following a Scottish Intercollegiate Guidelines Network (SIGN) recommendation and prescribing a licensed medicine outwith the

product licence needs to be aware that they are responsible for this decision, and in the event of adverse outcomes, may be required to justify the actions that they have taken.

Prior to prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF).

*Guidance on prescribing. In: The British National Formulary No. 59. London: British Medical Association and Royal Pharmaceutical Society of Great Britain; 2010.

Implementation of the Guideline

Description of Implementation Strategy

Resource implications of the key recommendations and key points to audit are available in section 14 of the original guideline document.

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

Implementation Tools

Audit Criteria/Indicators

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of atopic eczema in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2011 Mar. 34 p. (SIGN publication; no. 125). [62 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Mar

Guideline Developer(s)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

Source(s) of Funding

Scottish Executive Health Department

Guideline Committee

Guideline Development Group

Composition of Group That Authored the Guideline

Guideline Development Group: Dr Michael Tidman (*Chair*), Consultant Dermatologist, Royal Infirmary of Edinburgh; Ms Karen Braithwaite, Pharmacist, Aberlour Pharmacy, Moray; Ms Juliet Brown, Information Officer, SIGN; Mrs Jane Calder, Senior Dietitian, St John's Hospital, Livingston; Miss Jennifer Layden, Programme Manager, SIGN; Sister Janice Lowe, Clinical Nurse Specialist in Dermatology, Royal Infirmary of Edinburgh; Dr Pamela McHenry, Consultant Dermatologist, Royal Hospital for Sick Children, Glasgow; Dr Mary Mealyea, Associate Specialist in Dermatology, Royal Hospital for Sick Children, Glasgow; Dr Olivia Schofield, Consultant Dermatologist, Royal Infirmary of Edinburgh; Dr Tracey Secrett, General Practitioner, Bearsden; Dr Doug Smith, General Practitioner, Banchory; Sister Anne Smith, Director, Eczema Scotland, and Clinical Nurse Specialist in Dermatology, Royal Infirmary of Edinburgh; Ms Ailsa Stein, Programme Manager, SIGN; Dr Lorna Thompson, Programme Manager, SIGN; Mrs Eileen Wallace, Patient Representative, Stirling; Dr Stephen Wedderburn, General Practitioner, Aberdeen

Financial Disclosures/Conflicts of Interest

All members of the guideline development group made declarations of interest and further details of these are available on request from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .

Availability of Companion Documents

The following are available:

- Quick reference guide: Management of atopic eczema in primary care. Edinburgh (UK): Scottish Intercollegiate Guidelines Network (SIGN); 2011. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site .
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site .

In addition, section 14 of the original guideline document contains key points to audit.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 16, 2012. The information was verified by the guideline developer on January 23, 2012.

Copyright Statement

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